

REMARKS

Claims 1-10 and 28-30 are pending. Claims 11-27 have been canceled without prejudice. Support for the amendments is found throughout the specification and is depicted in the drawings. Reconsideration of the rejection is respectfully requested.

Claims 1-10 and 28-30 were rejected under 35 USC 112, second paragraph as being indefinite by claim 1 omitting a binding step and having a misplaced clause. Claim 1 has been amended to recite that the particles are allowed to bind. This language is somewhat different from the examiner's suggestion because the binding agent may not bind to all of the particles present in the sample, just those capable of binding to the binding agent and thus requiring all of the particles to bind is inappropriate.

Claims 1-10 and 28-30 were rejected under 35 USC 103 as being unpatentable over Nath. Nath is cited for using a vessel with a V shaped bottom where the slanted bottom is coated with antibodies that bind to antigens in an added sample. The examiner asserts that it would have been obvious to add a second slanted surface to concentrate particles for greater binding efficiency. This rejection is respectfully traversed.

A prima facie case for obviousness has not been made. No reference has been cited for adding a second slanted surface or performing the step of sedimenting particles across the first slanted solid phase. The examiner's assertion that it would have been obvious to concentrate particles before allowing contact is merely impermissible "hindsight" based on applicant's disclosure. Even if one desirable to concentrate the sample (an idea not taught by the reference), this does not suggest any particular structure or method for providing concentration.

Furthermore, the addition of a particle concentration means of any sort is contrary to the teachings of Nath. Indeed, Nath would probably be inoperable if particles were concentrated on only part of the V shaped bottom of her Microtiter plate. The Nath method measures the presence or absence of agglutination or flocculation to determining whether the test is positive or negative. See page 5, line 21-22, page 7, lines 15-20, page

13, line 3, page 14, line 2, page 16, line 8, page 17, line 5, Figures 2 and 3. When binding of the particles to the V shaped bottom occurs in Nath the entire slanted surface is coated. When binding of particle to the V shaped bottom does NOT happen, particles flocculate/agglutinate and sediment to be concentrated in one area.

It is illogical for one to concentrate the particles onto one area of the V-shaped bottom because it prevents the particles from binding to the entire area, which provides an indication of a positive or negative test. The examiner's proposed modification to the Nath assay would give the same result regardless of whether the test should have read positive or negative.

Still further, a flocculation/agglutination assay can only measure one reaction per vessel. Nath does not suggest any possible technique to detect two different particles simultaneously in the same vessel. This is claimed in claim 3. Likewise, there is no suggestion for plural binding agents as recited in claim 2.

Since Nath is performing a flocculation/agglutination assay, detection is made by presence or absence of flocculation/agglutination in a localized area or dispersed over the V shaped bottom of the vessel. There is no motivation to stain the results because detection was already done. Therefore, there is no motivation to stain as recited in claim 10.

The examiner's comment regarding using a density gradient to "obviate the need for removing unbound sample" is unclear as to how it would be used. Particles in the sample need to contact the slanted surface in order to bind to it. Using a density gradient to remove unbound particles would also seem to prevent particles from binding initially.

Accordingly, this rejection should be withdrawn.

Claims 1-10 and 28-30 were rejected under 35 USC 103 as being unpatentable over Anderson et al ('834). While Anderson et al disclose microbanding particles in a modified ultracentrifuge tube; the examiner further urges it obvious to immobilize binding reagents on the second solid phase to increase binding efficiency. This rejection is respectfully traversed.

The Anderson et al ('834) reference lacks any teaching of having a binding agent for the particles immobilized on a slanted surface. Anderson et al does not have any binding of the particles to the vessel walls ever occurring. Anderson et al specifically teach preventing the adherence of particles to the inner surfaces of the vessel. Note Anderson et al claims 6 and 22 where they state, "...the inner surfaces are coated with adhering polymer to prevent adsorption of biological particles." Therefore, Anderson et al lacks any motivation of ever binding any sample particles to the vessel walls by any means.

Also, the primary goal of Anderson et al is to have the particles band at a location based on density and/or sedimentation rate as stated in numerous locations in the ('834) patent. Binding would prevent them from banding based on sedimentation rate and/or density and thus prevent particle isolation in the desired "virus window". See column 7, lines 15-21, Figure 1. It would also prevent particle concentration in a microband in the lowest region of the ultracentrifuge tube because the particles would be bound on the slanted surface. It is in the lowest region that microbanding becomes sufficiently concentrated for easy detection. The net result of the modification of Anderson et al as set forth in the rejection would be to make the Anderson et al ('834) technique inoperable. Therefore, the examiner has not presented a prima facie case of obviousness for adding a binding agent to the Anderson et al ultracentrifuge tube. Accordingly, such a modification would not be obvious and thus the rejection should be withdrawn.

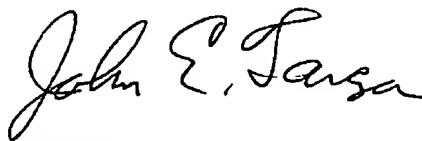
Furthermore, certain claims recite plural binding agents as mentioned above. Anderson et al is attempting to isolate a virus by recovering a band. There would be no motivation to use plural binding agents and no indication how they are to be arranged inside the ultracentrifuge tube. Accordingly, this rejection should be withdrawn.

CONCLUSIONS

In view of the amendments and comments above, the rejections have been overcome. Reconsideration, withdrawal of the rejections and early indication of allowance are respectfully requested.

If needed, applicants petition for an extension of time under the provisions of 37 CFR 1.136(a) for sufficient time to accept this response. The commissioner hereby is authorized to charge payment of any fees under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No.500933.

Respectfully submitted,



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